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ABSTRACT

Objective To gain insight into neonatal care providers' perceptions of deferred consent for delivery room (DR) studies in actual scenarios.

Methods We conducted semistructured interviews with 46 neonatal intensive care unit (NICU) staff members of the Leiden University Medical Center (the Netherlands) and the Hospital of the University of Pennsylvania (USA). At the time interviews were conducted, both NICUs conducted the same DR studies, but differed in their consent approaches. Interviews were audio-recorded, transcribed and analysed using the qualitative data analysis software Atlas.ti V.7.0.

Results Although providers reported to regard the prospective consent approach as the most preferable consent approach, they acknowledged that a deferred consent approach is needed for high-quality DR management. However, providers reported concerns about parental autonomy, approaching parents for consent and ethical review of study protocols that include a deferred consent approach. Providers furthermore differed in perceived appropriateness of a deferred consent approach for the studies that were being conducted at their NICUs. Providers with first-hand experience with deferred consent reported positive experiences that they attributed to appropriate communication and timing of approaching parents for consent.

Conclusion Insight into providers' perceptions of deferred consent for DR studies in actual scenarios suggests that a deferred consent approach is considered acceptable, but that actual usage of the approach for DR studies can be improved on.

What is already known on this topic?

- Conducting delivery room studies is much needed, but obtaining ethically valid informed consent for time-critical studies from distressed parents can be challenging.
- Deferring the consent process for delivery room studies can speed up patient accrual and reduce selection bias.
- Various delivery room studies reported usage of deferred consent, but indepth understanding of providers' views and experiences with this approach is lacking.

What this study adds?

- Providers acknowledge that a deferred consent approach for delivery room studies is needed and acceptable, but also reported concerns.
- Insight into providers' perceptions of deferred consent in actual scenarios suggests that actual usage of the approach can be improved on.
- Positive experiences with deferred consent were mostly attributed to appropriate communication and timing of approaching parents for consent.

INTRODUCTION

Conducting delivery room (DR) studies is much needed, but can be ethically problematic, as obtaining valid informed consent for time-critical studies from parents faced with an imminent premature birth can be challenging.[1–3] Neonates that require emergency resuscitation are often the most sick neonates, and excluding them from research would cause selection bias, resulting in decreased generalisability and less externally valid research.[4 5] Legislation and guidelines on conducting studies with an exception for informed consent in emergency situations were established, allowing investigators to enter neonates in study protocols that meet strict requirements without parental consent.[6–8] As soon as reasonably possible, parents are informed about their child's study participation (waiver of consent, as stipulated in American legislation) or informed and asked for permission to continue their child's study participation and to use already obtained data (retrospective, or deferred consent, as stipulated in European legislation).

Several studies reported usage of a deferred consent approach for DR studies.[9–17] Using a deferred consent approach can speed up patient accrual and reduce selection bias.[18 19] Concerns about using a deferred consent approach, such as concerns about the impact on the provider–parent relationship, were reported as well.[20 21] However, as jurisdiction and guidance for deferred consent vary, actual experience with deferred consent for DR studies is limited and indepth understanding of providers' views on deferred consent for DR studies is lacking.[22] As part of a larger project,[23 24] we conducted interviews with providers of neonatal intensive care units (NICUs) that participate in the same studies, but differ in their consent approaches. With this paper, we aim to gain insight into providers' perceptions of deferred consent for DR studies in actual scenarios.

METHODS

For a research project studying ethical aspects of improving DR management, semistructured interviews were conducted with NICU staff members working at the NICU of the Leiden University Medical Center (LUMC) in the Netherlands and the Hospital of the University of Pennsylvania (HUP) in the USA. The LUMC and the HUP are both tertiary perinatal centres with an average of 800 admissions a year.

Research at the LUMC and the HUP

Just as many NICUs, the LUMC and the HUP strive to improve the quality of their DR management. Both NICUs routinely record DR management. These recordings are used for plenary review meetings, as well as for education and for data collection for observational studies. When interviews were conducted, the LUMC and the HUP collaborated in two multicentre trials: a superiority trial comparing two initial sustained inflations combined with positive end-expiratory pressure (PEEP) with initial intermittent positive pressure ventilation combined with PEEP (Sustained Aeration of Infant Lungs (SAIL) trial),[25] and a study assessing the efficiency of a respiratory functioning monitor (MOnitoring Neonatal ResuscitationMONitoR trial; trial registration number: NCT03256578). At the HUP, neonates could only be entered into these study protocols after parental consent, obtained prior to randomisation, that is, prior to the delivery (prospective consent), whereas at the LUMC a deferred consent approach could also be used in case of an imminent delivery or when approaching parents for consent was considered inappropriate.

Experience with usage of a deferred consent approach differed strongly between NICUs: at the LUMC, a deferred consent approach was already used for various DR studies since 2014, whereas at the HUP a waiver of consent had been used for one observational DR study.

Data collection

Interviews were conducted by MCdB. Using semistructured interview guides, participants were questioned about their experiences with and perceptions of a deferred consent approach for DR studies. To produce maximum variation in the study sample, participants were selected through purposive sampling, that is, a non-probability sampling method that is commonly used in qualitative research to cover a range of potentially relevant perspectives.[26] Inclusion of participants continued until thematic saturation was reached on providers' perspectives on recording and reviewing neonatal resuscitation.[23]

Analysis

Data collection and analysis occurred simultaneously. Interviews were audio-recorded and transcribed. Data were first reviewed in a process of open coding, and subsequently data were thematically analysed. MCdB and MH independently coded several transcripts. During consensus meetings, main themes connected to deferred consent emerged. Using an iterative approach, providers were specifically asked about these themes in further interviews. The qualitative data analysis software program Atlas.ti (V.7.0), a software program that helps to sort, structure, describe and retrieve qualitative data,[27] was used to analyse data.

RESULTS

From February to December 2017, 46 NICU staff members were interviewed, including attendings, physician assistants, respiratory therapists, registered nurses and investigators involved in DR studies. Interviews lasted 45 min on average. Respondents differed in their experience with conducting DR studies and approaching parents for consent for study participation. Further participant characteristics are summarised in table 1.

Table 1 Participant characteristics

	LUMC (n=24)	HUP (n=22)	Total (N=46)
Male (%)	33	29	31
Age, median (range)	39 (26–54)	41 (28–77)	41 (26–77)
Years of experience at NICU, median (range)	9.2 (0.5–31)	10.7 (0.5–46)	9.9 (0.5–46)
Staff members (%)			
Attending	29	32	30
Neonatal fellow	13	27	20
Physician assistant	13	5	9
Respiratory therapist	N/A	9	4
Nurse practitioner	N/A	9	4
Registered nurse	29	22	26
Paediatric resident	13	0	7
Medical student	4	0	2
Involved in DR studies	13	9	11

DR, delivery room; HUP, Hospital of the University of Pennsylvania; LUMC, Leiden University Medical Center; N/A, not applicable; NICU, neonatal intensive care unit.

Although experience with usage of a deferred consent approach differed strongly between NICUs, similar perspectives were reported by providers of both centres. Four main themes were identified: acceptability of the deferred consent approach; the role of parents; intervention, standard of care and risk; and ethical oversight.

Acceptability of the deferred consent approach

Although providers reported to regard the prospective consent approach as the most preferable consent approach, they acknowledged that deferred consent is much needed to reduce selection bias, resulting in high-quality research that is generalisable to the whole population of neonates that require support at birth. Providers emphasised several benefits and concerns of both a deferred and a prospective consent approach (table 2).

Having first-hand experience with deferred consent for DR studies improved acceptability of the deferred consent approach. However, first-hand experience did not evidently improve acceptability of a deferred consent approach for the specific studies that were being conducted at the NICUs. Perceived appropriateness of a deferred consent approach for the MONitoR and the SAIL trials varied widely among providers, both with and without experience with deferred consent. Providers stated to feel comfortable with a deferred consent approach for observational studies using recordings of DR management, assuming that parents can ask for the recordings to be deleted. For other studies, providers reported that the appropriateness of a deferred consent approach needs to be considered explicitly. Providers reported various preconditions for usage of a deferred consent approach (table 3), with special emphasis on communication to the parents, the need to delete data when parents refuse study participation of their child, and interventions that do not add risk, pain or discomfort, and are close to the standard of care.

Providers who were experienced in approaching parents for deferred consent reported they sometimes felt constrained to do so. However, providers reported that despite these feelings, it is always important to obtain parental consent for continued study participation and the usage of already obtained data, as this

Table 2 Illustrative quotes of reported benefits and concerns of prospective and deferred consent

	Prospective consent	Deferred consent
Benefits	Gold standard. "In my opinion, a good investigator holds the responsibility to ask for consent prospectively. That's just the best way." (LHCP21)	Less abstract. "Well, some parents said: I am so happy we were not approached antenatally. We would not have had any idea of what we would have been consenting to." (LHCP02)
	Adds parental autonomy. "So I think that while we do provide some parental autonomy, we actually limit a lot of what they are allowed to say yes or no to. So I think when it's new studies, when it's other things, I feel like that sort of has to be part of the parental autonomy." (HHCP15)	Improves generalisability. "I think that if you want a representative study population, you just need to have the possibility. (…) And if you cannot include people that enter the hospital and directly give birth, you will draw conclusions that do not apply to these cases." (LHCP21)
	Relationship. "You are not going to tell them all these things afterwards. I think that would be sneaky. So for the relationship of trust it's very important." (LHCP20)	Improves informed consent. "And, you know, in the froze of preterm labour, an hour before she delivers, that might be not the best time to get consent from anybody. So, you actually make it a better consent if you do it afterwards." (HHCP24)
Concerns	Burden parents unnecessarily. "And it happens frequently that parents did consent, but that parents pass the study term. And for me it is very unpleasant to burden parents with study protocols they end up not being eligible for." (LHCP02)	Parents cannot refuse anymore. "But I also often notice that when parents are approached for deferred consent, they would easier consent as it has already been accomplished. And I do find that difficult, because it almost feels like that parents indicate they don't really have a choice." (LHCP07)
	Burden parents in a stressful situation. "These parents are suddenly in such another mode and oftentimes it's just not sound to burden these people with that question, like, do you wanna participate in this study? That's just of a secondary importance to them." (LHCP03)	Mistrust. "[I]f you are gonna say: we have already randomized, we have already done something different than we would otherwise do, that may stir up mistrust. (…) [T]hen they may think: well, what else are you gonna do to my child without me knowing about it?" (LHCP10)
	Too much information to process. "And, you know, there is so much to tell when you counsel parents, you are not gonna elaborate on scientific research or approach them for consent in such a difficult time." (LHCP06)	Relationship. "Because there only has to be one or two people who do have a problem with that. That would be very unpleasant. Especially when you are establishing a therapeutic relationship." (LHCP04)
	Potential benefit denied. "I think if there's a potential for benefit, that's going to be, what's the word I'm looking for, denied to the families, then I feel more inclined to offer deferred consent for them." (HHCP11)	Right not to participate in research. "Or there may be people that do not want to contribute to science at all, or that have other ideas about that. I do feel that we should respect that." (LHCP10)
	Selection bias. "And if you can only get prospective consent and you know you're gonna end up with this selected and somewhat biased population, I don't know on a population level that that's the best thing for preterms either." (HHCP03)	Selection bias. "I think if something went really well, they may be, you know, OK, I'll sign it. Whereas if you have a situation where something really didn't go well, I feel like if you just came to them and tell that mom that she lost her baby, like, you're not gonna get somebody who's gonna sign that paper." (HHCP16)
	Value of informed consent. "Like, to play devil's side, the difference between getting consent from a mother who is in actively birth, and very stressed, like are you really getting a true informed consent, are you really explaining it in issue, understanding it?" (HHCP23)	Impact on the image of research. "But you do risk that people would feel treated like guinea pigs. And if there's something you should not want to happen, it is that scientific research is gonna be labelled with 'guinea pigs'." (LHCP14)

HHCP, Hospital of the University of Pennsylvania healthcare professional; LHCP, Leiden University Medical Center healthcare professional.

would provide parents with at least some autonomy. Providers thus preferred a deferred consent approach over a waiver of consent approach.

Role of parents

An important theme in considerations about the acceptability of deferred consent for DR studies was parental autonomy. Some providers stated that autonomy about study participation sometimes seems to be the only autonomy parents facing an imminent premature birth have, thus highlighting the importance of prospective consent. On the opposite, several providers considered prospective consent inappropriate, as this places too much burden on parents. Many providers emphasised the parental right not to participate in research. Some providers suggested that the deferred consent approach could be strengthened by adding an antenatal opt-out for research in general.

An important concern of providers was that deferred consent changes the question you ask parents when approaching them for consent. Providers felt that approaching parents for deferred consent could be considered by parents as fait accompli, preventing parents to refuse continued study participation and the usage of already collected data. Some providers worried this could consequently result in parental mistrust or parents who feel their child was used as a 'guinea pig'. Experiences of Dutch providers, however, refute these concerns. Although interviewed providers reported to sometimes feel constrained by approaching parents for deferred consent, none of them had experienced a negative reaction from parents. According to providers, this was mostly due to appropriate communication and timing of approaching parents for deferred consent.

Intervention, standard of care and risk

When asked for the acceptability of deferred consent for DR studies, providers related acceptability to study interventions and the incorporated risk of study procedures. Study protocols using a deferred consent approach should preferably not be interventional, but if interventional, study interventions should be close to the standard of care, or comparing two standards of care. Some providers highlighted that comparative effectiveness studies comparing two standards of care could still incorporate risk if providers are not proficient in both methods. Furthermore, some providers considered that participating in interventional

Table 3 Illustrative quotes of reported requirements for usage of a deferred consent approach

Requirements	
Risk	"I think it depends on the level of risk of the research. I think if you're comparing things that are fairly equable, or you're just trying to collect information, there's not a really significant intervention, then I think a postnatal consent is completely justified. I think where you need an antenatal consent is where you really have, where you really expect that there's a significant amount of risk depending on the arm that the baby gets allocated to, or randomized to." (HHCP24)
Minimally invasive	"I can imagine that if you are gonna be invasive, or if you are gonna hurt the child, or if you need to do an intervention in order to be able to make some observations, or if you have to draw blood, well, that's another issue. In those cases you do want to have prospective consent." (LHCP11)
Proficient providers	"[W]e're really good at the protocol we know how to do, and sometimes when you introduce new protocols, even if it like has been shown to not be inferior in other studies, if we're not as good at doing it, like it may be inferior. So I think the providers also need to be proficient in that method, before, if there were gonna be a deferred consent there." (HHCP15)
Close to standard of care	"[I]f what you're doing isn't very far from the standard of care, you might be able to get away with a waiver of consent." (HHCP07)
No delay	"If there was a step that would delay somehow the care of the infant, then I think that would be a different issue." (HHCP06)
Clinical equipoise	"So then I think it takes a little bit more careful thought and, you know, data maybe from animal models. You know, success rates in intubation in small animals, to make sure that the risk is not a huge difference." (HHCP22)
No new drug	"[I]f I were a parent, I wouldn't what to be like, oh, we, we already, you know, gave your child an injection of this medication." (HHCP01)
Good communication	"So, I do think that parents, it just has to be asked properly, and deferred consent, fine! But that all depends on how you approach them and what you tell them. And whether you show some empathy towards them." (LHCP09)
Need for oversight	"It's not something some investigators just come up with, but something that has been reviewed by a committee of wise people. Independent people." (LHCP20)
Data deleted when parents refuse	"I think that would be fine. And, when parents refuse, I think you do have to delete the data." (LHCP12)

HHCP, Hospital of the University of Pennsylvania healthcare professional; LHCP, Leiden University Medical Center healthcare professional.

studies adds a risk, whereas others pointed out that not participating in these studies adds the risk of not receiving the best treatment.

Most providers emphasised minimal risk as a precondition for deferred consent for DR studies. However, there was no consensus on how minimal risk should be defined or valued. Providers did not agree on how much risk was involved in the studies that were being conducted at both NICUs when interviews were conducted. How much risk was involved in studies was mostly approached intuitively and varied widely among providers. Consequently, acceptability of a deferred consent approach for specific study protocols also differed considerably among providers.

Ethical oversight

Providers reported to feel backed up in using a deferred consent approach for DR studies by jurisdiction and ethical approval from the research ethics committee (REC). According to providers, reviewing study protocols that use a deferred consent approach for DR studies demands special expertise, but they were not sure whether the present REC actually has this expertise. Providers reported to be unsure about who could actually add this expertise to the REC. Some providers suggested that RECs should involve parents in decision-making about the appropriateness of consent procedures for specific study procedures, while others suggested that RECs should consult independent neonatologists.

DISCUSSION

Interviewed providers regarded the prospective consent approach as the most preferable approach, but acknowledged that deferred consent is needed for specific DR studies. However, providers reported concerns about parental autonomy, the right not to participate in research, approaching parents for consent and ethical review of study protocols that include a deferred consent approach. Providers furthermore differed in perceived appropriateness of a deferred consent approach for the DR studies that were being conducted at their NICUs. Providers with first-hand experience with deferred consent reported positive experiences that they attributed to appropriate communication and timing of approaching parents for consent.

Acceptance of a deferred consent approach varies considerably around the world.[28] Providers' acceptability of a deferred consent approach for actual paediatric emergency studies has been reported before.[20 21] Our study suggests that having first-hand experience with deferred consent improves acceptability of the deferred consent approach, which was also reported by Woolfall *et al*.[20] In our study, however, first-hand experience did not evidently improve acceptability of a deferred consent approach for the specific studies that were being conducted at the NICUs. Interviewed providers reported several factors that influence their considered appropriateness of the usage of deferred consent for actual study protocols.

Interviewed providers reported risk as an important factor that influences the appropriateness of deferred consent for specific DR study protocols. This was also reported by Foglia *et al*.[29] Risk is an important ethical issue in research involving children. Risks incorporated with the standard treatment in the DR should not be considered as risks of participating in a DR study.[30] However, as the recent controversy about the Surfactant, Positive Pressure, and Oxygenation Randomized Trial[31] illustrates, differentiating between the two can be challenging.[32]

In our study, providers too reported that defining risk can be challenging, and that this is often done intuitively. Challenges of risk classifications have been reported earlier. Rossi and Nelson[33] stated that judgements about risk are both normative and heavily intuitive in nature. Lantos *et al*[34] furthermore reported that risk classifications are marked by a high degree of variability and confusion. Local, regional or national differences in standards of care may furthermore complicate discussions about risk classifications of study protocols, which can be illustrated by the SAIL trial. In the Netherlands, the SAIL trial was considered as a comparative effectiveness study comparing two standards of care, as both interventions are commonly used in the Netherlands. Hence, this study was considered as a minimal risk study. In the USA, however, the study intervention of the SAIL trial was considered as an intervention that was not according to the

prevailing national guideline, which according to interviewed providers may add medicolegal risks. Consequently, some American providers would consider a deferred consent approach for the SAIL trial appropriate in the Netherlands, but inappropriate in the USA. Thus, the risk involved in specific study procedures may also be perceived differently due to study classification and associated local legislation.

Perceived risk of DR study procedures may vary due to many factors. Variations in perceived risk may not only exist within a group of stakeholders, as in our study, but may as well exist between stakeholder groups. These variations may explain why providers doubt whether the present RECs have the required expertise to review DR protocols that include a deferred consent approach: when minimal risk is considered as an important requirement for usage of deferred consent, but risk is perceived differently within and between stakeholder groups, then how do you decide whether a study incorporates minimal risk? Some interviewed providers suggested that inviting parents to RECs may provide a solution. Involving parents in the ethical review of study protocols was also recommended by Janvier *et al*,[35] but actual membership to an REC is considered complex. Janvier *et al*[35] therefore recommended to start with more easily achievable goals when planning to involve parents in research, such as the revision and improvement of consent forms, collaboration in the selection of research topics, or collaborating in patient recruitment. For DR studies, parents could be involved in discussions about perceived risk. Including also other stakeholders in this discussion, such as providers, RECs and the public, may allow to establish more comprehensive criteria for risk classifications for DR studies. These criteria may subsequently guide RECs in their decisions on the appropriateness of a deferred consent approach for a specific DR study. Furthermore, parent advisory boards could be involved in designing study protocols, or trial feasibility studies such as those performed by O'Hara *et al*[36] and Woolfall *et al*[3] can be conducted. Doing so may provide valuable insights into the perceived appropriateness of a deferred consent approach for specific DR studies.

Several interviewed providers reported that a prospective consent approach may burden parents and can thus be considered inappropriate. Ethical concerns about approaching parents faced with an imminent premature birth have been reported before.[1–3] According to American and European legislation, deferred consent can only be used when obtaining prospective consent is 'not feasible'[6] or 'not possible'.[7] Studying the impact of prospective consent on parents facing an imminent premature birth may help to decide whether possible impact on parents should be included in considerations about infeasibility or impossibility to obtain prospective consent for DR studies.

Concerns about the impact on parents were also reported for the deferred consent approach. Interviewed providers with first-hand experience with approaching parents for deferred consent suggested that these concerns can be overcome by appropriate communication with parents and timing of the consent procedure. Rich and Katheria[37] reported positive parental perceptions with deferred consent, as in the postnatal period there was more time in a non-stressful environment to inform parents about study procedures, allowing parents to truly recall and understand their child being in a DR study. Further studies on parental experiences with deferred consent, including experiences of parents of neonates that passed away or parents that refused deferred consent, may provide insight into the best way to approach parents for deferred consent. This may subsequently inform provider training on how to properly use a deferred consent approach for DR studies. As such, the deferred consent approach for DR studies can be improved and the actual usage of this approach can become more acceptable for both providers and parents.

Many providers reported the parental right not to participate in research, which complicated acceptability of deferred consent approach for DR studies. Providers therefore highlighted the importance of deferred consent in comparison with a waiver of consent, as this would provide parents with at least some autonomy. Interviewed providers furthermore suggested to adapt the deferred consent approach by adding an opt-out for research in general. This would respect the parental right not to participate in research. Other adaptations to the deferred consent approach could be considered as well. Chhoa *et al*[38] and Molyneux *et al*[39] reported positive experiences of providers with an adapted deferred consent approach, which consisted of a prospective oral assent and a written deferred consent. Such a consent approach would respect both parental autonomy and the right not to participate in research.

Another approach that may respect both parental autonomy and the right not to participate in research, an opt-out approach, may as well be considered. When using an opt-out approach, parents are provided with information regarding the research and their child's involvement. Their child's participation is then presumed, unless parents take action to decline to their child's participation. Consequently, parents are postnatally approached for explicit consent to use the data of their child. An opt-out approach is already included in the Australian National Statement on Ethical Conduct in Human Research.[40] More insight into stakeholders' perceptions is needed in order to assess the acceptability of such adaptations to the deferred consent approach.

CONCLUSION

Insight into providers' perceptions of deferred consent for DR studies in actual scenarios suggests that deferred consent for DR studies is considered acceptable, but that the actual usage of the approach can be improved on. This demands further understanding of stakeholders' experiences with, and perceptions of, deferred consent for DR studies, appropriate communication and timing of a deferred consent approach, risk classification for DR studies, and adaptations to the deferred consent approach that respect parental autonomy and the right not to participate in research. Doing so may improve both the acceptability and the actual usage of deferred consent for DR studies, which may consequently improve the quality of DR studies and the provided care to neonates that require support at birth.

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